TeleMedic Systems

JAN - 4 2008

2.0 510 (k) Summary

Data Prepared on: 24 October 2007
Date Revised on: 23 November 2007 (Revision A)

1. Submitter:
   TeleMedic Systems Ltd
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2. Contact Person

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3. Device Identification
   Trade Name / Proprietary Name: VitalLink^3 Mobile Vital Signs System
   Common Name: Portable vital signs monitor

4. Classification name and reference

Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)	CFR 870.2300, Class II Product Code: MWI
Transmitters and Receivers, Physiological signal, radio/frequency	CFR 870.2910, Class II Product Code: DRG

5. Indications for use
   The VitalLink^3 Mobile Vital Signs Monitor is intended for use as a portable vital signs monitor for patients who are remotely located from medical professionals. The system can be used to acquire and display vital signs data from patients in remote locations and transmit that data, in real time, to

medical professional located at a call centre / different location in order to help determine the patients transport needs.

6. Device Description

The VitalLink[3] System is a modular hardware/software system for acquiring, monitoring and/or communicating patient vital signs data.

The VitalLink[3] system acquires vital signs date from patients in remote locations (on land, in aircraft or on ships at sea) and communicates the data in real time to a medical professional at a call centre (Medical Service provider) in order to help determine the patient's need for transportation to a medical facility.

The VitalLink[3] System is comprised of the following discrete units:

a. The VitalLink[3] (VL3) monitors 4 vital sign parameters: 6/12 lead EKG, Non-invasive blood pressure (NiBP), blood oxygen saturation (SpO2), pulse rate and core temperature. The VitalLink[3] user interface includes a built in display for viewing collected data real time and a series of programmable soft keys for choosing communication preferences and manage communications with a medical service provider. The VitalLink[3] also has onboard memory for storing the data collected from the parameters.

   The VitalLink[3] is delivered to users in a fabric case with integrated compartments for the VitalLink[3], the sensor components, battery chargers, labelling, and consumable accessories.

b. Parameters: The EKG and SpO2 parameters identified in "6.a" above communicate with the VitalLink[3] via a Bluetooth RF link. The parameters are paired with a VitalLink[3] and the RF link tested just prior to when the device is packaged for shipping.

c. Clinical Interface: The Clinical Interface is a TeleMedic Systems developed proprietary software application that receives data from a VitalLink[3], decrypts the data and displays the information for use by medical professional / clinician in making a patient transport decision. The Clinical interface application is installed on a computer at the clinician's location.

d. Communication Options: There are six (6) possible means by which the VitalLink[3] can be configured to communicate with the Clinical Interface: Dialup telephone landline, direct wired connection to an IP network (Ethernet), satellite phone, satellite based data services, cellular phone and wireless 802-11 b/g networks.

7. Statement of Substantial Equivalence
TeleMedic Systems believes that the VitalLink[3] is a modification of the VitalLink1200 (K010732) as it has the same indications for use and does not include a change in the fundamental science incorporated in the predicate device. Further, through a detailed comparison establishes substantially equivalent to the predicate device.

The INTENDED USE of the modified device as described in it labelling HAS NOT CHANGED.

8. Performance Standards
Section 514 performance standards have not been promulgated for this device. There are voluntary standards for this device some of which are FDA recognized. The FDA recognized standards are identified with an "♦" in the following table.

Standard Number	Standard Organization	Standard Title	Rev	Date
♦ IEC60601-1	International Electrotechnical Commission	Medical Electrical Equipment. Part 1: General Requirements For Safety	2	30-Dec-1988
♦IEC60601-1-2	International Electrotechnical Commission	Medical Electrical Equipment. Part General Requirements For Safety 2. Collateral Standard; Electromagnetic Compatibility Requirements and Tests	2	29-Aug-2005
♦ IEC60601-1 (Amendment1)	International Electrotechnical Commission	Medical Electrical Equipment. Part 1: General Requirements For Safety - Amendment 1	-	13-Nov-1991
♦ IEC60601-1 (Amendment 2)	International Electrotechnical Commission	Medical Electrical Equipment. Part 1: General Requirements For Safety - Amendment 2	-	7-Mar-1995
♦ UL60601-1 (US Deviations to IEC60601-1)	Underwriters Laboratories	Medical Electrical Equipment. Part 1: General Requirements For Safety	1	25-Apr-2003
♦ IEC60601-2-27	International Electrotechnical Commission	Medical Electrical Equipment. Part 2: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	2	29-Aug-2005
DO-160	RTCA	Environmental Conditions and Test Procedures for Airborne Equipment	E	9-Dec-2004
IEC60529	International Electrotechnical Commission	Degrees of Protection Provided by Enclosures	2.1	27-Feb-2001

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Standard Number	Standard Organization	Standard Title	Rev	Date
IEC60068-2-6	International Electrotechnical Commission	Environmental testing - Part 2: Tests - Test Fc: Vibration (sinusoidal)	6	31-Mar-1995
IEC60068-2-32	International Electrotechnical Commission	Environmental testing - Part 2: Tests - Test Ed: Free fall	2	1-Jan-1975
IEC60068-2-32 (amd2)	International Electrotechnical Commission	Amendment 2 - Environmental testing. Part 2: Tests. Test Ed: Free fall	2	31-Oct-1990

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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TeleMedic Systems Ltd
c/o Mr. Gerald L. Buss
Chief Operating Officer
10 Billetfield
Taunton, Somerset
UNITED KINGDOM TA1 3NN

Re: K073094
VitalLink[3] Mobile Vital Signs System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: November 23, 2007
Received: December 10, 2007

Dear Mr. Buss:

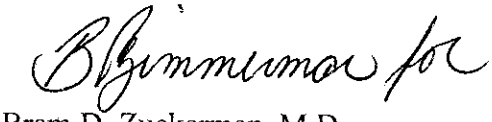
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 Indications for use Statement

510(K) Number: K073094

Device Name: VitalLink[3] Mobile Vital Signs System

Indications for use:

The VitalLink[3] (VL3) Mobile Vital Signs System is intend for use as a portable vital signs monitor for patients who are remotely located from medical professionals. The system can be used to acquire and display vital signs from patients in remote locations and transmit the data, real time, to a medical professional at a Medical Call Center / Medical Service Provider in order to help determine the patient's transportation needs.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XXX OR Over-the Counter Use _____
(Per 21 CRF 801.109)

Division Sign-off

510 (k) Number K073094